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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,768	09/22/2003	D. Russell Pflueger	D-3026CON	1359

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/667,768	Applicant(s) PFLUEGER, D. RUSSELL	
	Examiner Brian Szmal	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 30-45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/2/05; 6/10/04; 2/3/04 | 6) <input type="checkbox"/> Other: ____ |

Claim Objections

1. Claim 39 is objected to because of the following informalities: Claim 39 appears to claim the same matter as that in Claim 33. Appropriate correction is required.
2. Claim 44 is objected to because of the following informalities: In lines 2-3 of the claim, "the strip of rotating" is unclear and lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 30-33 and 36-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Fox (6,325,806 B1).

Fox discloses a material collection system and method and further discloses placing the device into a patient in order to obtain a tissue sample, the device having a cannula having an open distal tip and a rotational element disposed at least partially in the cannula; rotating the rotational element relative to the cannula, thereby drawing tissue into the open distal tip of the cannula; passing the material through the cannula; percutaneously introducing the device such that the distal tip of the cannula is placed in

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close proximity to the desired sample site; the cannula and rotational element are sized and positioned such that the rotation of the rotational element creates enough suction to draw the tissue into the distal tip of the cannula; the material is removed without additional suction or aspiration; the rotational element is effective in drawing tissue into the cannula as a substantially single continuous piece; collecting the removed material and observing the removed material; the rotational element includes a distal portion that extends beyond the distal tip of the cannula; the rotational element includes a distal portion that extends a distance in a range of about 0.02-1 inch beyond the distal tip of the cannula; the distal tip is beveled or substantially perpendicular with respect to the longitudinal axis of the cannula; and the collection chamber is structured to facilitate at least one of quantifying the removed material and observing the removed material. See Figures 1, 2, 3a, 3b; Column 11, lines 51-57; and Column 15, lines 26-29.

Even though Fox discloses the use of the device for obtaining a bone marrow sample, one of ordinary skill in the art would have been able to use the same device to obtain a regular tissue sample from another part in the body. Therefore, Fox inherently discloses the use of the device for other types of tissue samples.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox (6,325,806 B1) as applied to claim 30 above, and further in view of Shiber (4,883,458).

Fox, as discussed above, discloses a means of collecting tissue from a site, but fails to disclose the cannula has an outer diameter no larger than about 5mm; and the cannula has an outer diameter no larger than about 2mm.

Shiber discloses an atherectomy system and method and further discloses the cannula has an outer diameter no larger than about 5mm; and the cannula has an outer diameter no larger than about 2mm. See Column 7, lines 11-15.

Since both Fox and Shiber disclose means for removing tissue from the body using an auger-type device, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device and method of Fox to include a cannula diameter of no more than 5mm or 2mm, as per the teachings of Shiber, since it would provide a less invasive medical device for obtaining the tissue sample.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art of Sirimanne et al (6,136,014), Shapira (6,846,314 B2) and Steiner et al (6,783,532 B2) also disclose the use of auger-type elements to obtain samples of various tissue types.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-

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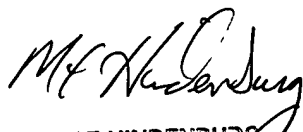
4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BS



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